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<p>(54) Title: SYSTEM AND METHOD FOR IMPROVING A RISK FOR A MONITORED CLIENT</p>		
<p>(57) Abstract</p> <p>A computer-controlled method of reducing the risk connected with a health condition of a patient includes determining an association between the patient's profile (250) which contains current information about the patient's condition, and a protocol domain space (200), accessing a protocol from the protocol-domain space (200) responsive to the association, and updating the profile responsive to the protocol. The protocol domain space (200) is three-dimensional and is bounded by a 'risk classification' axis (201), a 'clinical area' axis (203), and a 'content type' axis (205). A data cell (227) is located at the intersection of the coordinates and contains a set of protocols (229) each of which is designed specifically for its location in the protocol domain space (200).</p>		

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WO 00/33236

PCT/US99/28371

SYSTEM AND METHOD FOR IMPROVING A RISK FOR A MONITORED CLIENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Application No. 08/669,613, filed June 24, 1996 in the name of Stephen J. Brown, titled "On-Line Health Education and Feedback System Using Motivational Driver Profile Coding and Automated Content

- 5 Fulfillment", attorney docket number RYA-115, hereby incorporated by reference as if set forth in its entirety.

STATEMENT REGARDING FEDERALLY-SPONSORED RESEARCH

Not Applicable

REFERENCE TO MICROFICHE APPENDIX

- 10 Not Applicable

Background of the Invention

This invention relates to the field of health management, particularly to an automated interactive system and method for reducing the risk associated with a monitored client.

- 15 For example, the known art includes a number of health-management systems for providing outpatient services to patients with chronic health conditions such as asthma and diabetes. However, these systems are incapable of administering a treatment protocol responsive to the patient's current profile and of updating the profile in response to the administered protocol.

Summary of the Invention

- 20 It is accordingly desirable to provide an automated system and method for reducing the risk connected with a health condition of a client (or patient) whereby the client is

administered a treatment protocol responsive to the client's current profile and the patient's profile is updated responsive to the administered protocol.

Other advantages of the invention will become apparent after consideration of the ensuing description and the accompanying drawings.

5 In one embodiment of the invention, the computer-controlled method of reducing the risk connected with a health condition of a patient includes determining an association between the patient's profile and a protocol domain space, accessing a protocol from the protocol-domain space responsive to the association, and updating the profile responsive to the protocol.

10 **Description of the Drawings**

- Fig. 1 illustrates a computer system capable of using the invention in accordance with a preferred embodiment;
- Fig. 2A illustrates a protocol domain space representation in accordance with a preferred embodiment;
- 15 Fig. 2B illustrates a profile representation in accordance with a preferred embodiment;
- Fig. 3 illustrates a risk reduction process in accordance with a preferred embodiment;
- Fig. 4 illustrates protocol domain space creation process in accordance with a preferred embodiment; and
- 20 Fig. 5 illustrates adjust profile process in accordance with a preferred embodiment.

Description of the Preferred Embodiments

Notations and Nomenclature

The following 'notations and nomenclature' are provided to assist in the understanding of the present invention and the preferred embodiments thereof.

- 5 **Data Structure** — A data structure is an ordered arrangement of storage in memory for variables.

- 10 **Procedure** — A procedure is a self-consistent sequence of computerized steps that lead to a desired result. These steps are defined by one or more computer instructions. These steps are performed by a computer executing the instructions that define the steps. Thus, the term "procedure" can refer to a sequence of instructions, a sequence of instructions organized within a programmed-procedure or programmed-function, or a sequence of instructions organized within programmed-processes executing in one or more computers.

Related Applications

- 15 Inventions described herein can be used in combination or conjunction with inventions described in the following patent applications. These patent applications are hereby incorporated by reference as if fully set forth herein:

- Application Serial No. 09/041,809, filed November 21, 1997 in the name of Stephen J. Brown, titled "Phenoscope and Phenobase," assigned to the same assignee, attorney docket number RYA-136;
- Application Serial No. 08/666,242, filed June 20, 1996, in the name of Stephen J. Brown, titled "Health Management Process Control System," assigned to the same assignee, attorney docket number RYA-114.
- Application Serial No. 08/669,613 filed June 24, 1996, in the name of Stephen J. Brown and Erik K. Jensen, titled "On-line Health Education and Feedback System Using Motivational Driver Profile Coding and Automated Content Fulfillment," assigned to the same assignee, attorney docket number RYA-115.

- Application Serial No.08/732,158 filed October 16, 1996, in the name of Stephen J. Brown, titled "Multiple Patient Monitoring System for Proactive Health Management," assigned to the same assignee, attorney docket number RYA-116.
- Application Serial No. 08/814,293, filed March 10, 1997, in the name of Stephen J. Brown, titled "On-Line Health Education Using Composites of Entertainment and Personalized Health Information," assigned to the same assignee, attorney docket number RYA-119a.
- Application Serial No. 08/847,009 filed April 30, 1997, in the name of Stephen J. Brown, titled "Monitoring System for Remotely Querying Individuals," assigned to the same assignee, attorney docket number RYA-126.
- Application Serial No. 08/975,774, filed November 21, 1997, in the name of Stephen J. Brown, titled "Multi-User Remote Health Monitoring System," assigned to the same assignee, attorney docket number RYA-131a.
- Application Serial No. _____, Express Mail Mailing No. EE 261 914 722 US, filed September 23, 1998, in the name of Stephen J. Brown, titled "Dynamic Modeling and Scoring Risk Assessment," assigned to the same assignee, attorney docket number HHN-003.
- Application Serial No. _____, Express Mail Mailing No. EI 027 453 472 US, filed September 23, 1998, in the name of Stephen J. Brown, titled "Reducing Risk Using Behavioral and Financial Rewards," assigned to the same assignee, attorney docket number HHN-004.
- Application Serial No. _____, Express Mail Mailing No. EE 143 637 591 US, filed November 30, 1998, in the name of Stephen J. Brown, titled "Leveraging Interaction with a Community of Individuals," assigned to the same assignee, attorney docket number HHN-004.

Operating Environment

Fig. 1 illustrates a computer, indicated by general reference character 100, that incorporates the invention. The computer 100 includes a processor 101 that incorporates a central processor unit (CPU) 103, a memory section 105 and an input/output (I/O) section

107. The I/O section 107 is connected to an I/O device 111 (that can include a keyboard and/or a display device), a disk storage unit 113 and a CD-ROM drive unit 115. The CD-ROM drive unit 115 can read a CD-ROM medium 117 that typically contains a program and data 119. The CD-ROM drive unit 115 (along with the CD-ROM medium 117) and the disk storage unit 113 comprise a filestorage mechanism. Some embodiments of the invention 5 include a network interface 121 that connects the computer 100 to a network 123. An application program 125 generally resides in the memory section 105 after being loaded from the filesystem or a removable media such as the CD-ROM drive unit 115. One skilled in the art will understand that not all of the displayed features of the computer 100 need to be 10 present for the invention.

Fig. 2A illustrates a protocol domain space representation, indicated by general reference character 200, corresponding to a three-dimensional protocol domain space. One skilled in the art will understand that the protocol domain space may be n-dimensional, and that each axis in the protocol domain space can include more values than are presented in Fig. 15 2A. The protocol domain space 200 is three-dimensional and is bounded by a 'risk classification' axis 201, a 'clinical area' axis 203, and a 'content type' axis 205. The protocol domain space 200 can include other dimensions than the ones illustrated. These other dimensions include (without limitation) a medical condition and patient age.

The 'risk classification' axis 201 includes an 'unknown risk' classification 207, a 20 'high risk' classification 209, a 'medium risk' classification 211, and a 'low risk' classification 213.

The 'content type' axis 205 includes a 'symptom' classification 215, a 'behavior' classification 217, and a 'knowledge' classification 219.

The 'clinical area' axis 203 includes a 'feet classification 221, an 'eyes' classification 25 223, and a 'metabolic control' classification 225. One skilled in the art will understand that although biological areas pertaining to a particular health condition (for example diabetes) are used in a preferred embodiment, that other clinical areas can be used by other embodiments. These areas include device diagnostic areas, system failure modes, and similar diagnostic classifications.

30 A data cell 227 is located at the intersection of the provided coordinates. The data cell 227 contains (or references) a set of protocols 229 each of which is designed specifically for

its location in the protocol domain space 200. These protocols are used to interact with the patient (or the patient's healthcare provider). This interaction includes (without limitation) gathering information about the patient, measuring a medical or physiological parameter of the patient. Protocols are well defined in the above referenced incorporated applications. The 5 construction of the set of protocols 229 is subsequently described with respect to Fig. 4

Fig. 2B illustrates a profile representation, indicated by general reference character 250, corresponding to a profile. The profile 250 includes a 'clinical area' axis 251, a 'content type' axis 253, and an information area 255. The profile 250 is maintained in a profile database as shown in U.S. Application No. 08/669,613 (previously incorporated by reference 10 in its entirety). The profile contains current information about the patient's condition. For example, the information area 255 for a patient having a diabetic condition could contain information as to whether the patient has the knowledge that inspection of the toes is important; whether the patient regularly inspects the toes; and whether there are lesions between the toes. The information area 255 can also contain historical information regarding 15 the patient's historical conditions and information regarding how the patient responds to, and complies with supplied protocols. The content of the information area 255 is used to determine the risk classification for the patients with respect to a clinical area.

One skilled in the art will understand that an association is developed by evaluating the content of the profile 250. The association is used to select the data cell that contains the 20 set of protocols 229. Once the data cell is selected, a protocol is selected from the set of protocols 229 that, when presented to (and adhered to by) the specific patient, will reduce that patient's risk classification. The profile and the protocol domain space contain sufficient information to determine a 'protocol use history' that can be used to ascertain which protocols in the set of protocols 229 have been previously presented and the improvement of the risk 25 classification resulting from the previously presented protocols.

The protocol domain space 200 and the profile 250 can be represented in computer memory using data structures.

Fig. 3 illustrates a risk reduction process, indicated by general reference character 300, used to reduce a risk classification of a health condition of a specific patient. The specific 30 patient has a profile that can be obtained in a variety of ways including interaction between the specific patient and a monitoring device (such as the Health Buddy™ device or other monitoring devices described in the above referenced applications). The risk reduction

- process 300 initiates at a 'start' terminal 301 and continues to a 'select profile' procedure 302 that selects which profile to apply to the protocol domain space 200. The risk reduction process 300 continues to a 'determine association' procedure 303. The 'determine association' procedure 303 determines an association between the profile and a protocol
- 5 domain space. For example, if the profile has not been applied to the protocol domain space the association will indicate an unknown risk classification for the profile. However, if the profile has been previously applied to the protocol domain space, the profile will contain (or will contain information that can be used to obtain) the previously determined risk classification.
- 10 An 'access protocol' procedure 305 uses the association to locate a data cell in the protocol domain space and to select a protocol from the located data cell. The protocol is downloaded to the monitoring device where it executes. The protocol can also modify the profile using an 'adjust profile' procedure 307. The 'adjust profile' procedure 307 can be used to adjust (for example (without limitation), to modify) the risk classification in the
- 15 profile. The 'adjust profile' procedure 307 is subsequently described with respect to Fig. 5 and its associated text. The risk reduction process 300 can repeat back to the 'determine association' procedure 303 to obtain information responsive to the execution of the selected protocol.

One skilled in the art will understand that the method steps are performed by a
20 computer that the programmed computer contains mechanisms for performing the method steps.

Fig. 4 illustrates a protocol domain space creation process, indicated by general reference character 400, which can be used to assemble the protocol domain space 200. A person who has expertise in a knowledge domain creates a protocol that is responsive to a
25 profile that has particular characteristics. The protocol domain space creation process 400 initiates at a 'start' terminal 401 and continues to a 'create protocol' procedure 403. The 'create protocol' procedure 403 can lead the knowledge domain expert through a series of questions that develop a protocol that is responsive to a profile having particular characteristics. The knowledge domain expert can also manually create the protocol without
30 the assistance of a computer-based procedure. The protocol domain space creation process 400 continues to a 'location determination' procedure 405 that determines the location of a data cell in the protocol domain space 200 where the newly created protocol will be stored.

The location is responsive to an association that is developed from the information contained in the profile.

This association can be developed by comparing the information in the profile to threshold values to determine values for the coordinates into the protocol domain space 200.

- 5 Another method to develop this association is to apply a set of rules to the information contained in the profile to develop these coordinates. Another mechanism is to use Bayesian statistical techniques to develop the association. One skilled in the art will understand that other mechanisms exist that can be applied to develop these coordinates.

- A 'protocol access' procedure 407 loads the new protocol into the protocol domain space 200 at the specified location. The 'protocol access' procedure 407 also can retrieve a previously stored protocol so that the knowledge domain expert can modify or replace the protocol. The 'protocol access' procedure 407 also inserts the protocol into the data cell in a manner self consistent with the other protocols stored in the data cell (thus, subsequent selections of protocols from the data cell will include the possibility of selecting the newly inserted protocol). For protocols that interact with the profile, an 'enable protocol interaction' procedure 409 enables the protocol so that the protocol can be presented to the patient, and so that the protocol can interact with the profile as appropriate to indicate the presentation of the protocol; to force a selection of a subsequent protocol; to update information in the information area 255 of the profile. The protocol domain space creation process 400 completes through an 'end' terminal 411.

- The knowledge domain expert can use the protocol domain space creation process 400 to insert a set of instructional protocols that can contain a set of knowledge risk-determination protocols and a set of knowledge risk-reduction protocols. The set of knowledge risk-determination protocols is used to determine the patient's knowledge of the medical condition afflicting the patient. The set of knowledge risk-reduction protocols is responsive to the patient's knowledge (as determined by one or more of the set of knowledge risk-determination protocols). The set of knowledge risk-reduction protocols is designed to instruct the patient as to behavior and lifestyle that reduce the risk classification of the patient for the patient's condition.

- 30 The knowledge domain expert can use the protocol domain space creation process 400 to insert a set of symptom protocols that can contain a set of symptom risk-determination protocols and a set of symptom risk-reduction protocols. The set of symptom risk-

determination protocols is used to determine what symptoms have manifested in the patient. The risk-determination protocols are used when the patient's symptoms are unknown, or on a scheduled basis to obtain current information about the patient's symptoms. The set of symptom risk-reduction protocols is used to address the patient's current symptoms. For 5 example (without limitation), these protocols may include advising the patient to contact a healthcare provider, may cause a medical device to perform a measurement on the patient, may suggest that the patient take medication.

The knowledge domain expert can use the protocol domain space creation process 400 to insert a set of behavior protocols that can contain a set of behavior risk-determination 10 protocols and a set of behavior risk-reduction protocols. The set of behavior risk-determination protocols is used to determine the patient's behavior patterns. These protocols include determining how well the patient responds to new knowledge provided by the set of knowledge risk-reduction protocols; determining the patient's lifestyle behavior (for example, whether the patient consumes alcohol or smokes). The set of behavior risk-reduction 15 protocols provide the patient with information designed to provide incentives to the patient to modify his/her behavior to reduce the risk classification related to the behavior.

Fig. 5 illustrates an 'adjust profile' process, indicated by general reference character 500, that is invoked by the 'adjust profile' procedure 307 of Fig. 3. The 'adjust profile' process 500 initiates at a 'start' terminal 501 and continues to a 'profile adjust' decision 20 procedure 503. The 'profile adjust' decision procedure 503 determines whether the protocol has sufficient privilege and capability to directly modify the profile. If the 'profile adjust' decision procedure 503 determines that the protocol should have direct access to the profile, then an 'access profile' procedure 505 makes the profile available for modification. An 'adjust profile' procedure 507 executes the portion of the protocol used to directly modify the 25 profile and saves the modified profile. An 'activate protocol' procedure 509 activates the protocol. One skilled in the art will understand from the incorporated references that the 'activate protocol' procedure 509 can send the protocol to a remote medical device for execution. If, at the 'profile adjust' decision procedure 503, the protocol is not a profile adjust protocol or does not have sufficient privilege to modify a profile, the 'adjust profile' process 30 500 also continues to the 'activate protocol' procedure 509. Finally, the 'adjust profile' process 500 completes through an 'end' terminal 511.

One skilled in the art will understand that the invention provides an innovative approach to developing and enabling diagnostic protocols and behavioral modifications for a patient.

From the foregoing, it will be appreciated that the invention has (without limitation) 5 the following advantages:

- 1) provides an organizational construct for categorizing information that can be used to reduce the risk to a specific patient; and
- 2) enables a knowledge domain expert to develop a protocol that can be selected from information contained in a patient profile and to incorporate the protocol in a 10 healthcare system.

Although the present invention has been described in terms of the presently preferred embodiments, one skilled in the art will understand that various modifications and alterations may be made without departing from the scope of the invention. Accordingly, the scope of the invention is not to be limited to the particular invention embodiments discussed herein.

Claims

What is claimed is:

1. A computer-controlled method of reducing a risk classification of a health condition of a specific patient, said specific patient having a profile, said method including steps of:
 4. selecting said profile;
 5. determining an association between said profile and a protocol domain space;
 6. accessing a protocol from said protocol domain space responsive to said association, said protocol to reduce said risk classification; and
 8. presenting said protocol to said specific patient.
1. 2. The method of claim 1 further including adjusting said profile responsive to said protocol.
1. 3. The method of claim 1 wherein the step of accessing includes locating, responsive to said association, a data cell in said protocol domain space.
1. 4. The method of claim 3 wherein said data cell references a set of protocols.
1. 5. The method of claim 3 wherein said association includes a protocol use history for said profile.
1. 6. The method of claim 1 wherein adherence to said protocol reduces said risk classification.

- 1 7. A computer-controlled method for assembling a protocol domain space to interact
2 with a profile said method including steps of:
 - 3 creating a protocol responsive to said profile;
 - 4 determining a location in said protocol domain space for said protocol, said
5 location responsive to an association developed from said protocol; and
 - 6 accessing said protocol at said location in said protocol domain space.
- 1 8. The method of claim 7 wherein the step of accessing stores said protocol in said
2 protocol domain space.
- 1 9. The method of claim 7 wherein the step of accessing retrieves said protocol from
2 said protocol domain space responsive to said profile.
- 1 10. The method of claim 7 wherein said protocol domain space is n-dimensional and
2 includes at least one value selected from the group consisting of a clinical area, a
3 content type and a risk classification.
- 1 11. The method of claim 10 wherein said clinical area is a biological area.
- 1 12. The method of claim 10 wherein said content type is selected from the group
2 consisting of a behavior type, a symptom type, and a knowledge type.
- 1 13. The method of claim 12 wherein said knowledge type includes a set of instructional
2 protocols.
- 1 14. The method of claim 13 wherein said set of instructional protocols includes
2 protocols selected from the group consisting of a set of knowledge risk-
3 determination protocols and a set of knowledge risk-reduction protocols.
- 1 15. The method of claim 12 wherein said symptom type includes a set of symptom
2 protocols.

- 1 22. An apparatus having a central processing unit (CPU) and a memory coupled to said
- 2 CPU for reducing a risk classification of a health condition for a specific patient,
- 3 said specific patient having a profile, said apparatus including:
 - 4 a selection mechanism configured to select said profile;
 - 5 an evaluation mechanism configured to determine an association between said
 - 6 profile, determined by the selection mechanism, and a protocol domain space;
 - 7 an access mechanism configured to access a protocol from said protocol domain
 - 8 space responsive to said association, said protocol to reduce said risk classification;
 - 9 and
- 10 a presentation mechanism, responsive to the access mechanism, configured to
- 11 present said protocol to said specific patient.
- 1 23. The apparatus of claim 22 further including an adjustment mechanism configured to
- 2 adjust said profile responsive to said protocol.
- 1 24. The apparatus of claim 22 wherein the access mechanism includes a data cell
- 2 location mechanism configured to locate, responsive to said association, a data cell
- 3 in said protocol domain space.
- 1 25. The apparatus of claim 24 wherein said data cell references a set of protocols.
- 1 26. The apparatus of claim 24 wherein said association includes a protocol use history
- 2 for said profile.

- 1 42. A computer program product including:
 - 2 a computer usable storage medium having computer readable code embodied
 - 3 therein for causing a computer to reduce a risk classification of a health condition
 - 4 for a specific patient, said specific patient having a profile, said computer readable
 - 5 code including:
 - 6 computer readable program code configured to cause said computer to effect a
 - 7 selection mechanism configured to select said profile;
 - 8 computer readable program code configured to cause said computer to effect an
 - 9 evaluation mechanism configured to determine an association between said profile,
 - 10 determined by the selection mechanism, and a protocol domain space;
 - 11 computer readable program code configured to cause said computer to effect an
 - 12 access mechanism configured to access a protocol from said protocol domain space
 - 13 responsive to said association, said protocol to reduce said risk classification; and
 - 14 computer readable program code configured to cause said computer to effect a
 - 15 presentation mechanism, responsive to the access mechanism, configured to present
 - 16 said protocol to said specific patient.
- 1 43. The product of claim 42 further including computer readable program code
2 configured to cause said computer to effect an adjustment mechanism configured to
3 adjust said profile responsive to said protocol.
- 1 44. The product of claim 42 wherein the access mechanism includes a data cell location
2 mechanism configured to locate, responsive to said association, a data cell in said
3 protocol domain space.

- 1 45. A computer program product including
2 a computer usable storage medium having computer readable code embodied
3 therein for causing a computer to assemble a protocol domain space to interact with
4 a profile, said computer readable code including:
5 computer readable program code configured to cause said computer to effect a
6 protocol creation mechanism configured to create a protocol responsive to said
7 profile;
8 computer readable program code configured to cause said computer to effect a
9 domain space addressing mechanism configured to determine a location in said
10 protocol domain space for said protocol, said location responsive to an association
11 developed from said protocol; and
12 computer readable program code configured to cause said computer to effect
13 an access mechanism configured to access said protocol at said location in said
14 protocol domain space.
- 1 46. The product of claim 45 wherein the access mechanism is further configured to
2 store said protocol in said protocol domain space.
- 1 47. The product of claim 45 wherein the access mechanism is further configured to
2 retrieve said protocol from said protocol domain space responsive to said profile.
- 1 48. The product of claim 45 wherein said protocol domain space is n-dimensional and
2 includes at least one value selected from the group consisting of a clinical area, a
3 content type and a risk classification.
- 1 49. The product of claim 48 wherein said content type is selected from the group
2 consisting of a behavior type, a symptom type, and a knowledge type.
- 1 50. The product of claim 48 wherein said risk classification is selected from the group
2 consisting of an unknown risk, a low risk, a medium risk, and a high risk.

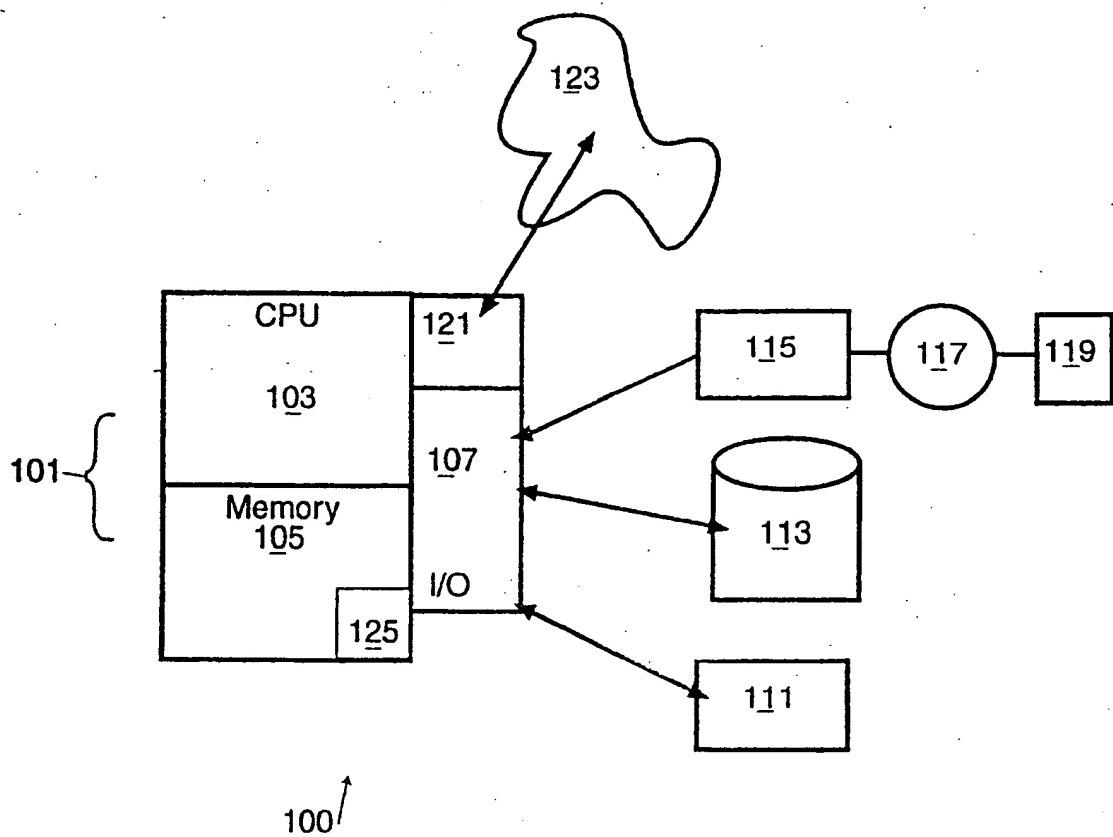


Fig. 1

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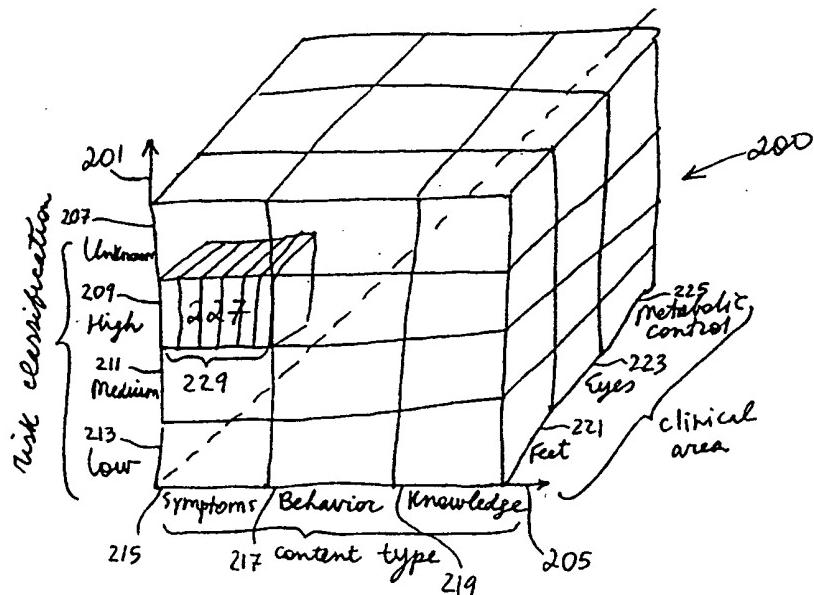
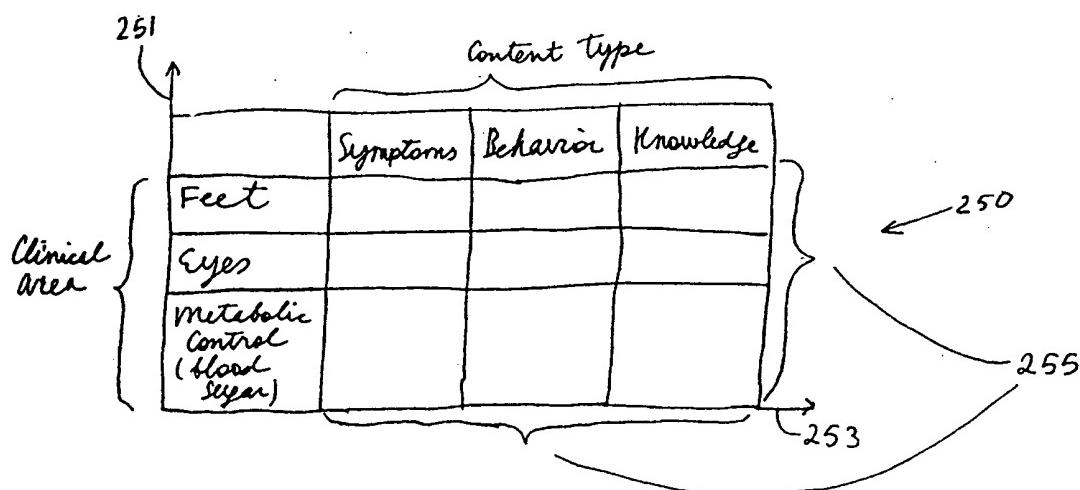


FIG. 2 A



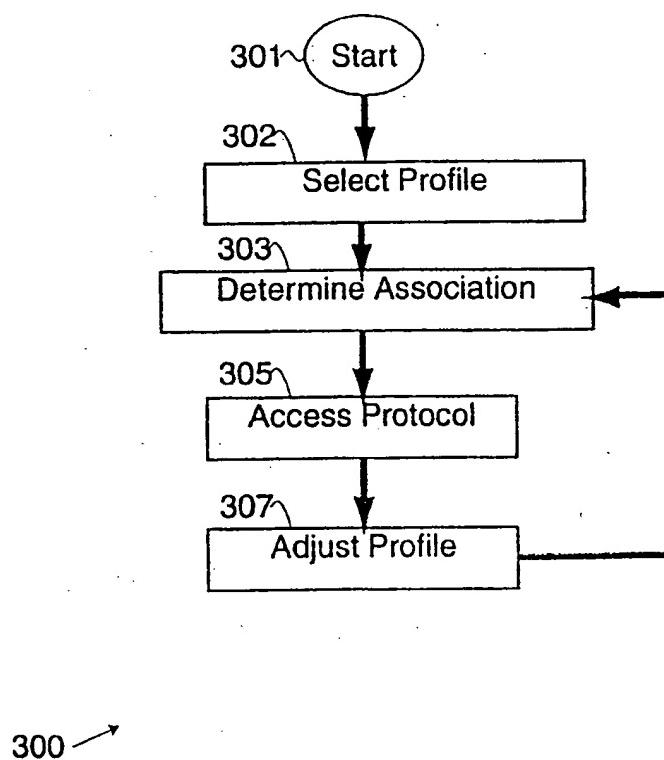


Fig. 3

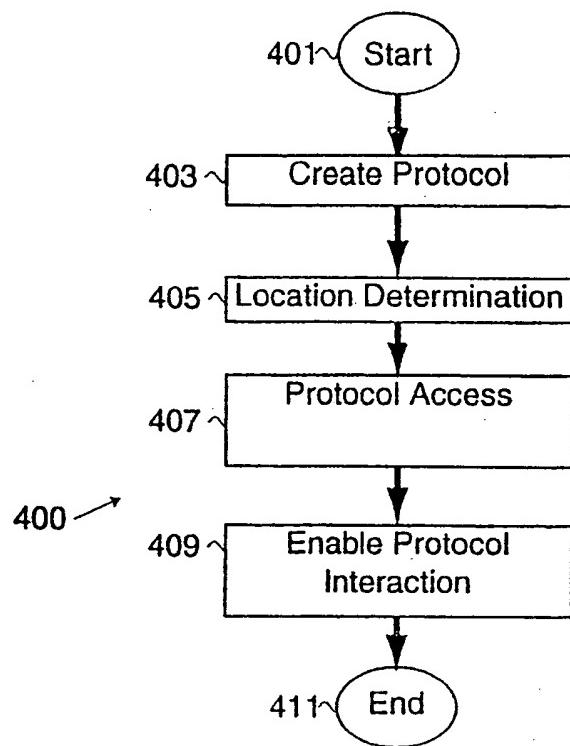
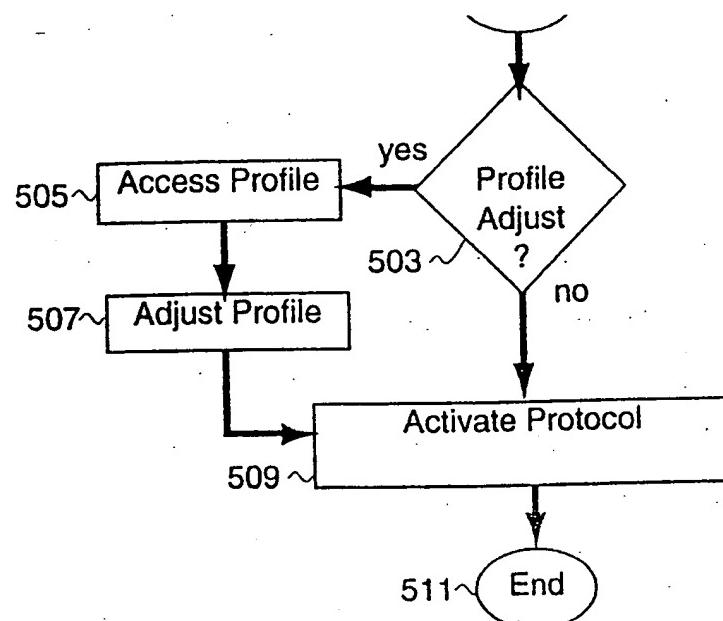


Fig. 4

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500 →

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/28371

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G06F 15/00
US CL : 705/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 705/1-3

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,032,119 A (BROWN ET AL.) 29 FEBRUARY 2000, ABSTRACT, COLUMN 5, LINE 39 TO COLUMN 7, LINE 18.	1-52
A, P	US 5,960,403 A (BROWN) 28 SEPTEMBER 1999, SEE ABSTRACT AND COLUMN 14, LINE 22 TO COLUMN 16, LINE 41.	1-52
A, P	US 5,956,689 A (EVERHART, III) 21 SEPTEMBER 1999, SEE ABSTRACT AND COLUMN 7, LINE 34 TO COLUMN 10, LINE 52.	1-52
A, P	US 5,953,704 A (McILROY ET AL.) 14 SEPTEMBER 1999, SEE ABSTRACT.	1-52
A	US 5,924,074 A (EVANS) 13 JULY 1999, SEE ABSTRACT AND COLUMN 14, LINE 26 TO COLUMN 15, LINE 67.	1-52

Further documents are listed in the continuation of Box C. See patent family annex.

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Date of the actual completion of the international search

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